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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,913	01/25/2002	Harish C. Joshi	E2690/268902	3014

23370 7590 07/23/2002

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EXAMINER
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JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/23/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/056,913

Applicant(s)

JOSHI ET AL.

Examiner

Dwayne C Jones

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-22 are pending.
2. Claims 1-22 are rejected.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of tumors, does not reasonably provide enablement for the prevention of tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The cancer therapy art remains highly unpredictable, and no example exists for the efficacy of a single product against tumors generally. Specifically, Internal Medicine, 4<sup>th</sup> Edition, Editor-in-Chief Jay Stein, Chapters 71-72, pages 699-715, teaches that the various types of cancers have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. It is also known that certain tumors are dependent upon estrogen for their induction or stimulation (e.g. breast tumors) and others are not, see U.S. Patent No. 4,605,661 and 4,916,144. Based on this state of the art, an estrogen inhibitor would be expected to be effective against those that are dependent upon

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estrogen for their induction, but not against those that do not depend upon estrogen for their induction. In addition, applicant has provided no guidance or working examples teaching one skilled in the art how to determine which of the countless products used in claims 19-22 would be effective against which tumors. As evidenced by the references noted above, one would not expect all of the compounds of the instant invention to be effective against all tumors. Therefore, based on the unpredictable nature of the invention and state of the prior art, the lack of guidance and working examples, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason supports this rejection. Claim 19 states that the "method for the treatment of neoplastic diseases, comprising: (a) administering to a mammal in need of such treatment an effective amount of a composition comprising a compound of the formula . . . ." However, the claim does not list the (b) component of this composition. It is recommended that the following should be performed to either insert – (b) – before the phrase, "in combination with another tumor therapy for the treatment or prevention of tumors." or to remove the " (a) ".

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Yahya et al. in view of Hyon et al. of U.S. Patent No. 5,100,669. Al-Yahya et al. teach of compound No. 1, (see page 438). Al-Yahya et al. also teach that noscapine is an alkaloid, (see page 409). Hyon et al. teach of administration of various types of pharmaceuticals, namely anticancer agents in a drug delivery system that is release-controlled with polylactic acid type microspheres, (see abstract and columns 1, 3-5). It is well known in the art that many alkaloids, such as noscapine, possess pharmacological activities. The determination of specific dosages, modes of administration as well as suitable excipients is well within the purview of one of ordinary skill in the art to prepare a noscapine derivative in a suitable delivery preparation along with pharmaceutically acceptable salts and excipients.

10. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Yahya et al. in view of Bar-Shalom et al. of U.S. Patent No. 5,213,808. Al-Yahya et al. teach of compound No. 1, (see page 438). Al-Yahya et al. also teach that noscapine is an alkaloid, (see page 409). Bar-Shalom et al. teach of the delivery of active substances, which includes anticancer agents, via the controlled-release of the pharmaceutically active substances with a polymer matrix, (see abstract and columns 1-2). Accordingly, it would have been obvious to one having ordinary skill in the art to delivery a pharmaceutically active substance, such as noscapine, to an individual in need of such treatment in a controlled-release delivery system, such as that taught by the prior art reference of Bar-Shalom et al.

11. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sam et al. in view of Hyon et al. of U.S. Patent No. 5,100,669. Sam et al. teach that the opium alkaloid of noscapine possesses none of the undesirable effects of narcotics, and it does possess various pharmacological properties, such as central nervous system activity and bronchodilation activity, (see page 1755). The prior art reference of Hyon et al. teaches of administration of various types of pharmaceuticals, namely anticancer agents in a drug delivery system that is release-controlled with polylactic acid type microspheres, (see abstract and columns 1, 3-5). Clearly, the determination of a mode or method of administration is well within the purview of the skilled artisan. Accordingly, the skilled artisan would have been motivated to employ the delivery system of Hyon et al. in order to administer the pharmaceutical of noscapine in a controlled release form as taught by Hyon et al.

12. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sam et al. in view of Bar-Shalom et al. of U.S. Patent No. 5,213,808. Sam et al. teach that the opium alkaloid of noscapine possesses none of the undesirable effects of narcotics, and it does possess various pharmacological properties, such as central nervous system activity and bronchodilation activity, (see page 1755). Bar-Shalom et al. teach of the delivery of active substances, which includes anticancer agents, via the controlled-release of the pharmaceutically active substances with a polymer matrix, (see abstract and columns 1-2). One having ordinary skill in the art would have been motivated to utilize the teachings of Bar-Shalom et al. to administer or delivery the pharmaceutically active substance of noscapine to an individual because the determination of specific dosages, modes of administration as well as suitable excipients is well within the purview of one of ordinary skill in the art

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

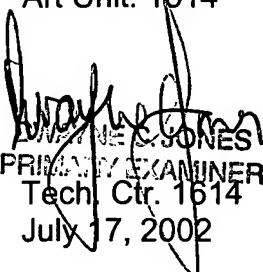
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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DWAYNE C. JONES  
PRIMARY EXAMINER  
Tech. Ctr. 1614  
July 17, 2002